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### PART 7—ENFORCEMENT POLICY

#### Subpart A—General Provisions

Sec.

- 7.1 Scope.
- 7.3 Definitions.
- 7.12 Guaranty.
- 7.13 Suggested forms of guaranty.

# Subpart B [Reserved]

# Subpart C—Recalls (Including Product Corrections)—Guidance on Policy, Procedures, and Industry Responsibilities

- 7.40 Recall policy.
- 7.41 Health hazard evaluation and recall classification.
- 7.42 Recall strategy
- 7.45 Food and Drug Administration-requested recall.
- 7.46 Firm-initiated recall.
- 7.49 Recall communications.
- 7.50 Public notification of recall.
- 7.53 Recall status reports.
- 7.55 Termination of a recall.7.59 General industry guidance.

# Subpart D [Reserved]

# Subpart E—Criminal Violations

7.84 Opportunity for presentation of views before report of criminal violation.

- 7.85 Conduct of a presentation of views before report of criminal violation.
- 7.87 Records related to opportunities for presentation of views conducted before report of criminal violation.

AUTHORITY: 21 U.S.C. 321–393; 42 U.S.C. 241, 262, 263b-263n, 264.

SOURCE: 42 FR 15567, Mar. 22, 1977, unless otherwise noted.

# Subpart A—General Provisions

#### § 7.1 Scope.

This part governs the practices and procedures applicable to regulatory enforcement actions initiated by the Food and Drug Administration pursuant to the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) and other laws that it administers. This part also provides guidance for manufacturers and distributors to follow with respect to their voluntary removal or correction of marketed violative products. This part is promulgated to clarify and explain the regulatory practices and procedures of the Food and Drug Administration, enhance public understanding, improve consumer protection, and assure uniform and consistent application of practices and procedures throughout the agency.

[43 FR 26218, June 16, 1978, as amended at 65 FR 56476, Sept. 19, 2000]

#### § 7.3 Definitions.

- (a) Agency means the Food and Drug Administration.
- (b) Citation or cite means a document and any attachments thereto that provide notice to a person against whom criminal prosecution is contemplated of the opportunity to present views to the agency regarding an alleged violation.
- (c) Respondent means a person named in a notice who presents views concerning an alleged violation either in person, by designated representative, or in writing.
- (d) Responsible individual includes those in positions of power or authority to detect, prevent, or correct violations of the Federal Food, Drug, and Cosmetic Act.
- (e) [Reserved]
- (f) Product means an article subject to the jurisdiction of the Food and Drug Administration, including any